UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: ZIMMER NEXGEN KNEE IMPLANT PRODUCTS LIABILITY LITIGATION	)	**MDL No. 2272**
	)	**Master Docket No. 11 C 5468**
KATHY L. BATTY,	)	
Plaintiff,	)	
v.	)	**No. 12 C 6279**
ZIMMER, INC., ZIMMER HOLDINGS, INC., and ZIMMER ORTHOPAEDIC SURGICAL PRODUCTS, INC.,	)	**Judge Rebecca R. Pallmeyer**
Defendants.	)	

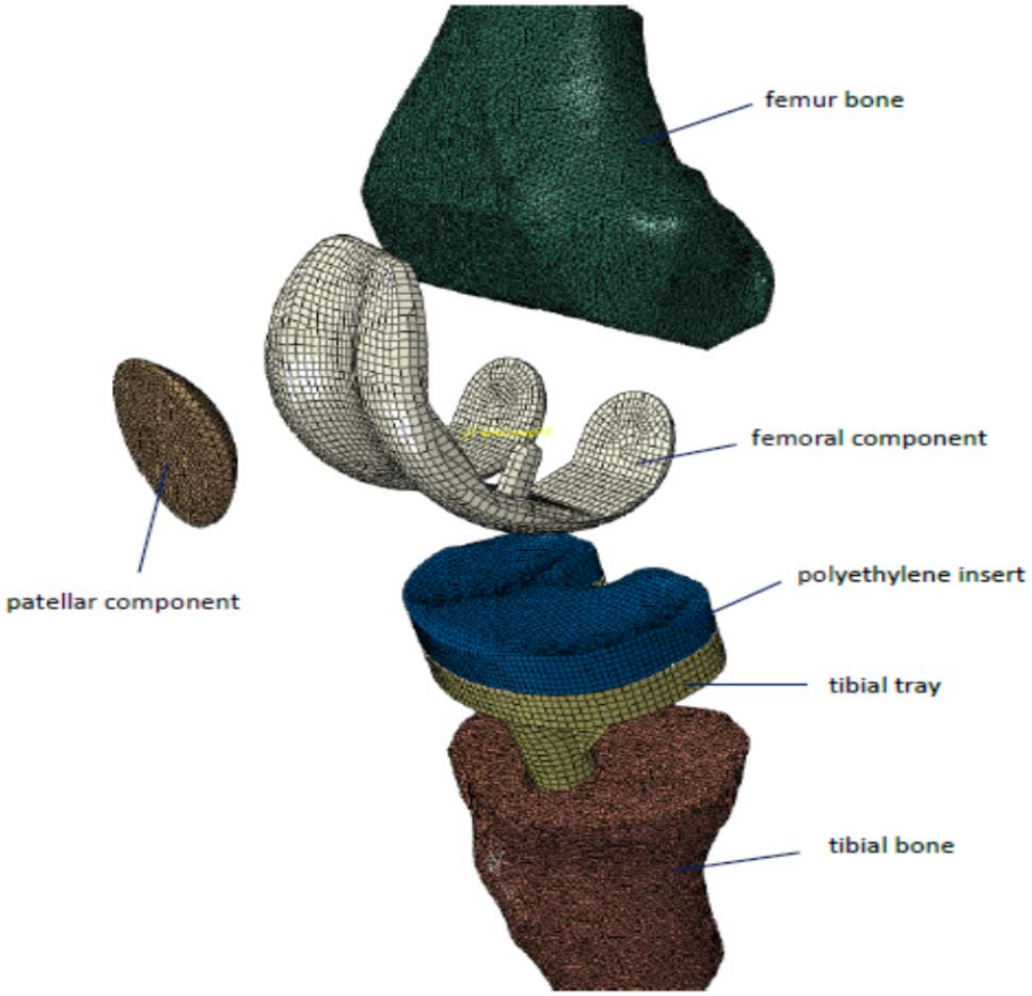
MEMORANDUM OPINION AND ORDER

Kathy Batty is one of hundreds of Plaintiffs who have sued Defendants, Zimmer, Inc. and its affiliates (collectively, "Defendant" or "Zimmer"), manufacturers of the Zimmer NexGen Flex Knee system. Plaintiffs, who have had the NexGen Flex system implanted, allege that the femoral and tibial components of the system are prone to premature loosening, resulting in pain and loss of movement. Ms. Batty's case has been chosen for a "bellwether" trial. Both parties have identified several expert witnesses. In earlier rulings [1536], [1539], the court considered challenges to three of Ms. Batty's proposed experts, Dr. Thomas Brown, Dr. Joseph Fetto, and her treating physician, Dr. Alan Klein. In this opinion, the court addresses Plaintiff's objections to expert testimony from one of Zimmer's proposed experts, Dr. Darryl D'Lima [1313]. For the reasons set forth here, those objections are overruled.

BACKGROUND[1]

[1] The court has described the facts of the case in detail in its earlier opinions, *see In re Zimmer NexGen Knee Implant Products Liab. Litig.*, No. 11-CV-5468, 2015 WL 3669933 (continued . . .)

Plaintiff Kathy Batty suffers from degenerative joint disease in both knees. In April 2009, her treating physician, Dr. Alan Klein, performed total knee replacements on both of Ms. Batty's knees. The knee implant replaces the top part of the shin bone (the tibia) and the bottom part of the thigh bone (the femur). The tibial component of a knee implant consists of a metal tray that sits on top of the tibia and a stem that extends downward into the tibia. Seated on top of the flat metal tray of the tibial component is a polyethylene surface that serves as the point of contact for the femoral component. The femoral component attaches to the bottom of the femur:



(N.D. Ill. June 12, 2015); *In re Zimmer NexGen Knee Implant Products Liab. Litig.*, No. 11-CV-5468, 2015 WL 3799534 (N.D. Ill. June 17, 2015), and provides only a short summary here.

(Construction and Validation of a Model of Knee Flexion, Ex. D to Report of Daryl D'Lima, Ex. 1 to Pl.'s Mem. [1313-1], hereinafter "Ex. D to D'Lima Rep.," 3.) The components can be cemented to the bone, or the components can bond directly to the bone without the use of cement, as the bone grows into the implant.

Dr. Klein implanted a NexGen LPS-Flex Gender Solutions femoral component (the "NexGen Flex") and a NexGen Stemmed Tibial Component Option in each of Ms. Batty's knees. These components, the model at issue in these lawsuits, are designed to enhance the patient's flexion capacity to 155 degrees, significantly more than earlier implants, including Zimmer's own original knee implant model (the "NexGen Standard"). Dr. Klein chose to cement Ms. Batty's implants. Just over a year after her surgeries, however, in July 2010, Ms. Batty began to experience pain in both knees. She had the implants replaced in April and May of 2011. In this litigation, Ms. Batty alleges that the Flex design caused the implants to prematurely loosen from the bone by increasing the forces and strain put on the implant.

Zimmer has retained Dr. Daryl D'Lima to create a computer model to predict the stresses and forces created by the NexGen Flex implants. Dr. D'Lima is a biomechanical engineer who serves as the director of Orthopaedic Research at Scripps Health, where he oversees all research projects and trains orthopedic fellows. (Expert Report of Dr. Darryl D'Lima, Ex. 1 to Pl.'s Mem. [1313-1], hereinafter "D'Lima Rep.," 1.) Dr. D'Lima was initially trained as an orthopedic surgeon. He received his medical degree in 1982 from LTM Medical College in India, and completed his residency and internship at the same institution. (*Id.*) He practiced orthopedic surgery in India for 6 years before moving to the United States in 1996 to pursue a two year research fellowship in hip and knee arthroplasty at Scripps Clinic in California. (*Id.*; Dep. of Darryl D'Lima, Ex C to Zimmer Resp. [1446-3], hereinafter "D'Lima Dep.," 7:20–25.) Following the fellowship, he continued at Scripps as the Head of the Joint Mechanics Laboratory. (D'Lima Rep. at 1.) Dr. D'Lima obtained a Ph.D. in bioengineering from the University of California, San Diego in 2007. (D'Lima Rep. at 1.)

To predict the forces acting on the knee implant, Dr. D'Lima explained, he used a process called Finite Element Analysis ("FEA"), which is a computer simulation technique used to model the real-world behavior of physical structures. The physical structure being modeled is subdivided into components, and each component is assigned fixed characteristics intended to mimic the real-world item being modeled. The fixed characteristics include material properties; for example, a scientist would assign a particular density to the digital model of a bone, chosen to mimic the patient's own bone density. Components are also assigned certain fixed parameters and constraints; for example, the model sets a standard for how much pressure or strain a bone or muscle can experience before breaking or rupturing, or imposes limits on the directions in which a bone can move.

Dr. D'Lima's FEA includes models of the femur and tibia bones, quadriceps muscles, patella, and the various components of the knee implant. (Ex. D to D'Lima Rep. at 3; NexGen LPS and NexGen LPS Gender Solutions Flex Models of Knee Flexion, Ex. F to D'Lima Rep. [1446-1], 2–5.) To develop various models of knee implants, Dr. D'Lima utilized computer-aided design ("CAD") files from Zimmer. (Ex. F to D'Lima Rep. at 1.) Dr. D'Lima used a special software program that constructs a three-dimensional model of the geometry and structure of a bone from a CT scan. (Ex. D to D'Lima Rep. at 1; Ex. F to D'Lima Rep. at 2.)

To model the cement interface between the bone and the implant, Dr. D'Lima relied in part on a previously published FEA by Zelle et al. (Ex. D to D'Lima Rep. at 1; Jorrit Zelle et al., *Does High-Flexion Total Knee Arthroplasty Promote Early Loosening of the Femoral Component?*, J. OF ORTHOPAEDIC RESEARCH 976, 977–78 (July 2011), Ex. F to Zimmer Resp. [1446-6], hereinafter "Zelle.") Zelle et al. conducted an FEA that modeled the cement interface in a high-flexion knee made by DePuy, another joint manufacturer, to evaluate whether femoral loosening is more likely in implants designed for high flexion, due to increased tensile and shear stresses. (Zelle at 976.) Dr. D'Lima's study applied the same material properties used by Zelle et al. for the cement. (Ex. F to D'Lima Rep. at 4.) But Dr. D'Lima deviated from Zelle et al.'s

approach in two ways: First, Zelle et al. assumed a continuous one-millimeter-thick layer of cement across the entire femoral component, though in practice, the surgeon ordinarily applies cement only to certain "pockets." (*Id.*) Dr. D'Lima attempted to mimic those pockets in his effort to shape the cement interface model. (*Id*. at 4, 6.) A second difference between D'Lima's work and that of Zelle et al. is that Zelle simulated only the bond between the cement and the implant, and did not separately consider the cement-bone interface. (*Id.* at 4.) Dr. D'Lima decided to address these bonds separately by creating two components for the model: a bone-cement interface and a cement-implant interface, (*id.* at 4–5), an approach later adopted in a published study by van de Groes et al. (*Id.* at 4) (citing van de Groes, de Waal-Malefijt, and Verdonschot, *Probability of Mechanical Loosening of the Femoral Component in High Flexion Total Knee Arthroplasty Can Be Reduced by Rather Simple Surgical Techniques*, 21 KNEE 209 (2014).)

The model Dr. D'Lima developed has variable inputs to represent different circumstances and patients. In this case, Dr. D'Lima's variables include the weight of the patient, the flexion angle, and the design of the implant. Dr. D'Lima then applied certain "boundaries and constraints" to the modeled components. For example, he modeled an ankle joint that simulated a foot firmly planted on the ground, which would not slip or rotate. He also prevented the simulated hip joint from moving from side to side or from front to back. In doing so, he simulated the motion of a patient performing a squat with his or her back perfectly straight, without leaning forward. He allowed the knee to flex up to 155 degrees. To model the contact between thigh and calf that results from such a squat, Dr. D'Lima relied on the input parameters used in two previously published FEA models, which had been experimentally validated in patients. (D'Lima Dep. at 226:23–227:2.) Finally, Dr. D'Lima utilized a model for calculating the pressure between the femoral component and polyethylene insert on the tibial component, which he had previously validated and published in a 2008 study. (D'Lima Decl., Ex. D to Zimmer Resp. [1446-4], hereinafter "D'Lima Decl." ¶ 6) (citing Darryl D. D'Lima et al., *In*

Vivo Contact Stresses During Activities of Daily Living After Knee Arthroplasty, 26 J. ORTHOPAEDIC RESEARCH 1549 (2008).)

Finally, the model produces certain outputs to provide answers to the experimental questions, in this case these: (1) in an average female patient conducting a single squat, are there any significant differences in the magnitude or location of the forces acting on the knee between the NexGen Standard and the NexGen Flex designs (Ex. F to D'Lima Rep. at 1), and (2) in a patient of Ms. Batty's weight and approximate bone size, what forces act on (a) the interface between the femoral component and the bone and (b) the tibial component's polyethylene surface during a single squat at 128 degrees of flexion, which Dr. D'Lima understood to be Ms. Batty's highest recorded flexion angle.[2] (NexGen LPS and NexGen LPS Gender Solutions Flex Models representing Patient KB, Ex. G to D'Lima Rep. [1313-1], hereinafter "Ex. G to D'Lima Rep.," 1.) To answer these questions, Dr. D'Lima calculated a variety of outputs from his model, including: (1) overall joint contact forces operating on the knee joint, (2) the stress on the interface between the femoral bone and the cement, (3) the stress on the interface between the cement and the femoral implant, and (4) the strain and pressure on the tibial polyethylene insert.

To validate his model, Dr. D'Lima input data specific to an actual patient referred to as "JW." JW has a "telemetrized" knee implant, meaning that his tibial component has devices in it that can measure the forces acting on the tibial component. (D'Lima Dep. at 35:2–9.) Dr. D'Lima input JW's weight, his knee implant design, and his specific bone shape based on CT scans. Dr. D'Lima asked JW to squat, and recorded the forces in the knee at various flexion angles. He recorded the greatest forces at 73 degrees of flexion, and Dr. D'Lima then ran his computer model with a flexion angle of 73 degrees. Dr. D'Lima compared the model's

[2] Dr. D'Lima also conducted "subject specific" analyses of two other bellwether plaintiffs, Randy Pudwill and Ramona Diano, but the court does not address them specifically.

calculation for the overall contact forces to the measurements taken by JW's implant and found them to be "very close," though he did not provide the exact measurements:

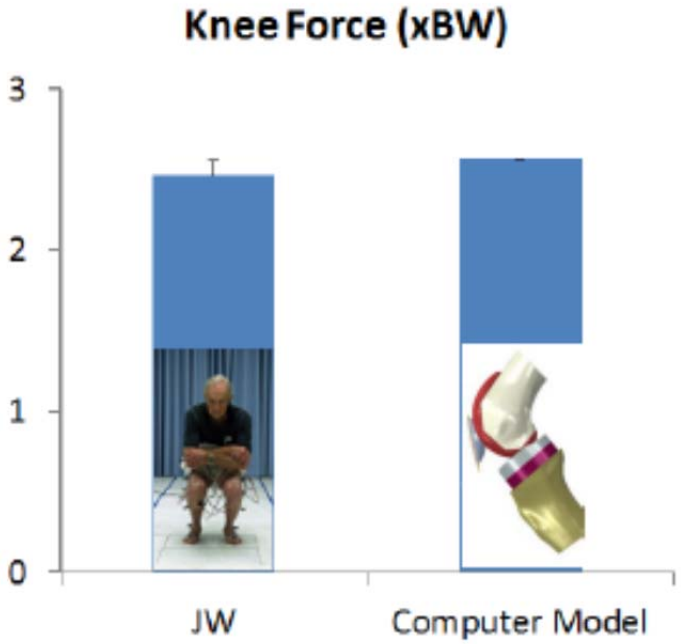


Figure 5: Maximum forces recorded during squatting matched those calculated by the computer model.

(Ex. D to D'Lima Rep. at 6.) Dr. D'Lima was unable to compare the model's calculations for the interface stresses, however, because measurement of interface forces in living patients is not yet technically feasible. (D'Lima Dep. at 116:22–25.)

Using the FEA models he created, Dr. D'Lima ran two experiments. First, in a model using an average female patient's characteristics (weight, bone size, and bone density), he compared the forces generated by the NexGen Standard design to those generated by the NexGen Flex implant at various flexion angles ranging from 50 to 155 degrees. This comparison was intended to isolate the effect of the design: "Since everything else in the model was kept the same, only the design of the femoral component and the tibial insert, and the femoral bone cuts would be responsible for any differences in the stresses generated." (Ex. F to D'Lima Rep. at 9.) Dr. D'Lima concluded that "in all the outcome measures analyzed, the Zimmer NexGen LPS Gender Solutions Flex design performed equivalent to or better than the Zimmer NexGen LPS Standard design." (Ex. F to D'Lima Rep. at 11.)

He then adjusted the model to reflect a patient of Ms. Batty's weight and at her highest recorded degree of flexion (128 degrees), and compared the Standard and the Flex designs, concluding again that "in all the outcome measures analyzed, the . . . Flex design performed equivalent to or better than the . . . Standard." (Ex. G to D'Lima Rep. at 2.)

DISCUSSION[3]

Plaintiffs urge the court to exclude Dr. D'Lima's testimony as unreliable under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.,* 509 U.S. 579 (1993). Plaintiff asserts that the FEA is unreliable because it was not properly validated.[4] Plaintiff presents an article which she contends sets forth the standards for validating an FEA model and casts doubt on Dr. D'Lima's efforts. (Andrew E. Anderson, Benjamin J. Ellis, and Jeffrey A. Weiss, *Verification, Validation and Sensitivity Studies in Computational Biomechanics*, 10 COMPUTER METHODS IN BIOMECHANICS AND BIOMEDICAL ENGINEERING 171 (2007), Ex. 2 to Pl.'s Mot. to Exclude D'Lima [1313-2], hereinafter "Anderson.") Anderson et al. identify two kinds of errors that can undermine an FEA model: computational errors, such as rounding errors, and modeling errors, that occur based on "inconsistencies between the model and physical system," such as using incorrect "geometry, boundary conditions, material properties, [or] governing . . . equations." (Anderson at 173.) According to Plaintiff, Dr. D'Lima's validation experiment suffered from several modeling errors that render his FEA model unreliable: (1) Dr. D'Lima only validated his results against one patient, JW, who was physically very different from Ms. Batty in terms of bone size and weight, and had a different implant made by DePuy; (2) Dr. D'Lima did not validate the model's predictions for the stresses acting on the interfaces between the bone and implant; (3) the validation was performed at just 73 degrees of flexion, well below the flexion

[3] The court assumes familiarity with the *Daubert* standards set forth in its earlier opinion, *see In re Zimmer NexGen Knee Implant Products Liab. Litig.,* No. 11-CV-5468, 2015 WL 3669933, at *6–7 (N.D. Ill. June 12, 2015), and declines to repeat them here.

[4] Plaintiff does not contest Dr. D'Lima's qualifications or the relevance of his testimony. The court, therefore, discusses only the reliability of Dr. D'Lima's analysis.

angles at issue in this case, which range from 120 to 155 degrees; and (4) the interfaces themselves were modeled differently in the validation experiment than they were in the experiments concerning Zimmer's knees. (Pl.'s Mem. in Supp. of Mot to Exclude Testimony of Daryl D'Lima [1312], hereinafter "Pl.'s Mem.," 5, 8–12, 15.)

Before the court addresses these specific concerns, it reviews the scientific standards for FEA models used in biomechanics. "The purpose of the *Daubert* inquiry is to scrutinize proposed expert witness testimony to determine if it has 'the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'" *Lapsley v. Xtek, Inc.*, 689 F.3d 802, 805 (7th Cir. 2012) (quoting *Kumho Tire Co.*, *Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999)). *Daubert* does not require that an expert's opinions be unassailable: the court will not "take the place of the jury to decide ultimate issues of credibility and accuracy." *Id.* at 805. Because the FEA is only a simulation, it is inevitable that some variables are assumed or neglected. But those limitations appear to be accepted in the scientific community, so long as they are reasonable and acknowledged by the author. Zelle et al., for example, constructed an FEA model to evaluate the interface stresses in high flexion knee implants. (Zelle at 977–78; D'Lima Decl. ¶ 7.) That study assumed a consistent one-millimeter-thick interface of cement, to "simplify the interface analysis," even though the cement actually is applied in pockets, and may be unevenly distributed depending on the surgical technique. (Zelle at 982.) Despite this assumption, and the authors' recognition that it "may have affected the femoral fixation strength," (Zelle at 982), the study was accepted for publication in a peer-reviewed journal.

The article Plaintiff cites as evidence of methodological standards itself recognizes that FEA models will inevitably have some inaccurate assumptions. For example, Anderson et al. clarify that certain modeling errors may be acknowledged by the author of the experiment, without rendering the model unreliable. (Anderson at 173.) They also note that "[t]he required level of accuracy for a particular model will depend on its intended use," and that, "[w]hat is considered 'good enough' must be based on engineering judgment, the intended use of the

model and peer review." (Anderson at 173, 182.) In fact, the authors note that "[c]omputational models in biomechanics are sometimes developed to simulate phenomena that cannot be measured experimentally and require model inputs that are unknown or may vary by several orders of magnitude." (Anderson at 182.) While those models "may appear to contradict the above-described validation process since measurements and predictions cannot be compared directly," the models can still provide insight to complex systems, albeit under a more narrow interpretation and with more limited applicability. (Anderson at 182; *see also id.* at 174 (the extent of validation experiments "may affect the overall applicability and utility of the computational model, not vice versa.").) Zelle et al. is again an instructive example. According to the authors, "the analysis of the interface stress state was our main objective," (Zelle at 978), even though those forces could not be validated in live patients. (D'Lima Decl. ¶ 7.)

As Anderson et al. recognize, the practice of making assumptions and calculating outputs that cannot be validated limits the degree to which scientists will extrapolate from a particular FEA; that practice does not, however, cast a shadow on the FEA's methodological soundness. For purposes of this court's *Daubert* analysis, then, the accuracy of the underlying assumptions goes to the relevance and weight of the evidence, rather than its reliability. That is, if the model makes assumptions that do not reflect reality, or Ms. Batty's particular circumstances, a reasonable jury would give that evidence less weight because it reduces the model's predictive value. But because no FEA can perfectly mimic reality, to show that Dr. D'Lima's methodology is unreliable, Plaintiff must do more than argue it makes inaccurate assumptions.

The court turns now to Plaintiff's more specific criticisms. First, Plaintiff argues that Dr. D'Lima's model does not accurately reflect Ms. Batty's personal characteristics. Plaintiff asserts, for example, that the validation cannot be extrapolated to Ms. Batty because JW and Ms. Batty are too physically distinct, as "JW was an 80 year old man – Batty was 54 at the time of her primary implants," and "JW had an entirely different design of implant." (Pl.'s Mem. at 15.)

Plaintiff also criticizes as inaccurate various assumptions Dr. D'Lima used in the model, such as a lack of irregularities on the surface of the bone, evenly spread cement with a uniform strength of attachment, and a firmly planted foot. (Pl.'s Mem. at 15.)

The court concludes that the differences between JW and Ms. Batty do not render the model unreliable. In the validation experiment, Dr. D'Lima used inputs in the model that were specific to JW—his bone geometry, his implant design, his method of bonding (un-cemented), and his weight—and, using those variables, computed a value for overall contact forces in the knee. The computed value closely matched the experimental value, suggesting good predictive value. Dr. D'Lima then swapped JW's characteristics for those corresponding to Ms. Batty's; he used a CT scan of a femur that is approximately the size of her bone and input her implant design, her method of bonding (cemented), and her weight. JW's model assumed a rigid contact between the bone and the implant. (*See* D'Lima Dep. at 118:7–9; *see generally* Ex. D to D'Lima Rep. (no modeling of a separate bone-implant interface).) Because Ms. Batty had a cemented implant, Dr. D'Lima changed the way he modeled the bone-implant interface, making adjustments to the model to reflect Ms. Batty's particular implant design. As noted earlier, this approach to modeling the cement as involving two distinct components—a bone-cement interface and a separate cement-implant interface—has been repeated in a published study by van de Groes, and appears to be methodologically acceptable. In essence, to conduct his experiment representing Ms. Batty, Dr. D'Lima swapped in Ms. Batty's variables for JW's. (*See* D'Lima Dep. at 102:10–22.) Changing the variables, however, does not suggest that the underlying formula is incorrect.

Similarly, the court concludes that Dr. D'Lima's inability to measure the interface stresses does not require that his opinion be excluded, as Plaintiff argues. (See Pl.'s Mem. at 15–18.) Dr. D'Lima explained that measuring those stresses in live patients is not technically feasible and Plaintiff has presented no evidence suggesting otherwise. (D'Lima Dep. at 116:22–25.) The fact that Dr. D'Lima's model attempts to calculate and predict a variable that

cannot be validated does not entirely defeat the predictive value of the experiment. Anderson et al. recognized that scientists can use FEA models to better understand forces that cannot be measured experimentally. (Anderson at 182.) The inability to fully validate the interface stresses might mitigate the importance of this evidence for Zimmer because its predictive value is not certain, but it does not mean that Dr. D'Lima's methodology falls below current scientific standards.

Finally, the court turns to Plaintiff's concern that Dr. D'Lima failed to validate his model at more than one angle of flexion. This matter requires slightly more consideration. Anderson et al. explain that "[r]epeated" validation experiments are critical to "provide[] confidence in the use of the model for decision making." (Anderson at 172.) Dr. D'Lima, however, offers only one comparison between his model's predictions and the measured forces, at 73 degrees. (Ex. D to D'Lima Rep. at 6.) Plaintiff concludes that the model is unreliable because without validation at other angles, there is no assurance of the model's predictive value, and in fact, for flexion greater than 73 degrees, the model predicts forces significantly higher than those recorded by JW's implant. (Pl.'s Mem. at 12; D'Lima Dep. at 100:13–25.)

Zimmer acknowledges that Dr. D'Lima did not validate the model at higher flexion angles, but asserts the model is nonetheless reliable. (Zimmer Resp. at 5.) Dr. D'Lima explains that the discrepancy between the model's predictions and the measured forces results from the model's assumption that the patient is squatting with a straight back: squatting with a straight back generates more force on the knee, and also requires significant muscle strength. (D'Lima Decl. ¶¶ 8–10.) Most knee replacement patients cannot perform a deep squat with a straight back; instead, patients lean their torsos forward, shifting their center of gravity and alleviating some pressure on the knee. (D'Lima Decl. ¶ 10.) Dr. D'Lima chose to validate the model at 73 degrees because that was the angle at which JW's implant recorded the highest forces; as JW squatted deeper, the forces on the knee actually declined as his torso leaned forward. (D'Lima Dep. at 100:6–101:3.) Thus, above 73 degrees, the measurements from JW's implant were no

longer measuring the same activity that the FEA was modeling. The FEA modeled a more strenuous activity, and therefore produced higher force predictions than measured in JW.

With this understanding, Plaintiff's argument again amounts to a criticism that the model does not realistically reflect patient activity. (*See* Pl.'s Reply [1483], 6) ("Rather than the model imitating reality, reality is altered to fit the model.") But as Dr. D'Lima acknowledges, the model was "not trying to predict exactly what [forces]. . . . Kathy Batty had." (D'Lima Dep. at 101:6–9.) Rather, Dr. D'Lima asserts that his model represents a "worst-case scenario," predicting significantly higher forces than a patient would experience in reality.[5] (D'Lima Dep. at 101:9–14, 115:16–22, 252:23–25.) This was, thus, in Anderson et al.'s terms, an "acknowledged error" introduced by Dr. D'Lima in order to create a model of more aggressive activities and forces in the knee. Plaintiff will have the opportunity to criticize the model for diverging from realistic activities, but as explained above, those criticisms go to the accuracy and weight of the model, not its reliability.

CONCLUSION

The court shares some of Plaintiff's concerns regarding the absence of repeated validation at multiple flexion angles. As explained here, however, the court believes that Dr. D'Lima's FEA follows similar methodology and is as intellectually rigorous as FEA models published by other scientists in the peer-reviewed literature. Plaintiff's motion [1311] is, therefore, denied.

[5] Dr. Brown challenges this characterization, noting that the assumption of a squat with a straight back may have inadvertently introduced a force pushing the femur forward, so that the pressure was more centered on the tibial component, rather than located on the posterior edge, where it is more likely to cause strain on the polyethylene insert and micromotion of the tibial component. (Dr. Brown's Resp. to Dr. D'Lima's Report, Ex. 4 to Pl.'s Mem. [1313-4], 3.) That may be, but this criticism goes to the accuracy and weight of the evidence, not its admissibility.

ENTER:

Dated: August 13, 2015

REBECCA R. PALLMEYER
United States District Judge